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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,592	08/02/2001	Ingvar Mats Ferby	100564-00064	2983

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EXAMINER	
SNEDDEN, SHERIDAN	
ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 09/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/889,592	FERBY ET AL.	
	Examiner	Art Unit	
	Sheridan K Snedden	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 June 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37-48* is/are pending in the application.

4a) Of the above claim(s) *none* is/are withdrawn from consideration.

5)☒ Claim(s) *37,38,41-43,45,47 and 48* is/are allowed.

6)☒ Claim(s) *39, 40, 44 and 46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Amendment

1. This Office Action is in response to Paper filed 25 June 2003. Claims 17-36 have been canceled. Applicant's addition of new claims 37-48 is acknowledged. Claims 37-48 are pending.

Withdrawal of Objections and Rejections

2. The objections and/or rejections not explicitly restated or stated below are withdrawn.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 39 and dependent claims 44 and 46 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a DNA sequence of SEQ ID NO: 1 and DNA encoding the protein of SEQ ID NO: 2, does not reasonably provide enablement for all sequences that would hybridize to the above sequences or all genomic sequences from all species for the above sequences. Furthermore, the specification does not does not reasonably provide enablement for all genomic sequences from all species for the sequence of SEQ ID NO: 1. The specification does not give any guidance as to the full range of all existing sequences that could hybridize to the DNA sequences above or to all genomic sequences for all species of SEQ ID NO: 1 as recited in the instant claims. In In re Wands, 8 USPQ2d 1400 (1988), factors to be

considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the breadth of the claims,
3. the state of the prior art,
4. the predictability or lack thereof in the art,
5. the amount of direction or guidance present,
6. the presence or absence of working examples,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

Each factor is addressed below on the basis of comparison of the disclosure, the claims and the state of the prior art in the assessment of undue experimentation.

1) the nature of the invention;

In the instant case, Applicants are claiming a DNA sequence (SEQ ID NO: 1 or 2) encoding a protein (SEQ ID NO: 3 or 4) that may be used for inducing oocyte maturation or modulating cell proliferation.

2) the breadth of the claims;

As recited in claim, the breadth of the claim is directed to all sequences that would hybridize to DNA encoding the protein of SEQ ID NO: 3 or 4. All such proteins would have the capability to induce oocyte maturation or modulate cell proliferation.

3) the state of the prior art; and,

DNA hybridization techniques are routine procedures in the art and may be optimized by altering the parameters of salt and detergent concentration, time and temperature.

The sequences of SEQ ID NO: 1 - 4 are not described in the art. Additionally, no apparent homologs or genomic sequences to the DNA and protein are identified by a search of the art. Therefore, these is no guidance present in the prior art as the conditions of hybridization to be used using the DNA sequence.

4) the amount of direction or guidance presented;

5) the presence or absence of working examples;

The specification and claims fail to define stringent conditions. On page 3, the specification mentions that the conditions for hybridization are stringent but fail to provide clear instruction as to the parameters of salt and detergent concentration, time and temperature. None of the examples provided in the specification define the conditions of hybridization that are to be read in the claim.

The instant specification does not give any guidance to the genomic sequence encoding the protein. Page 2 of the specification teaches that cDNA was prepared and cloned into expression vectors. Example 1-4 teaches the preparation and use of a cDNA library. The specification fails to provide any discussion as to the genomic sequence, such as identification of introns and exons or position of the gene on the chromosome.

Likewise, there is no guidance for identifying sequences from all species, such as what sequence elements, domains, and biological function are critical that would define a family of sequences.

6) the predictability or unpredictability of the art;

DNA hybridization techniques may be used for quantification of a specific DNA or may be used to search sequences of like sequence identity. The determinants of hybridization are the percent identity of the hybridizing DNA molecules and the parameters discussed above. However, without specific conditions of hybridization, the results are unpredictable. For instance, Ishibashi *et al.* teach a cDNA that shares a sequence identity of 60.7% between nucleotides 381 and 902 of SEQ ID NO: 1. The cDNA taught be Ishibashi *et al.* would not have similar biological activity as the DNA sequence claimed in the present invention. Thus, not all sequences that would hybridize to SEQ ID NO: 1 would have the same function used for inducing oocyte maturation or modulating cell proliferation. The person of skill in the art would not be able to identify sequences used for inducing oocyte maturation or modulating cell proliferation with any predictability given the direction provided by the specification. Furthermore, the identification of all genomic sequences from all species for all sequences which hybridize to the sequence of SEQ ID NO: 1 would also be unpredictable.

There is no disclosure of any specific starting material or any of the conditions under which a process can be carried out, and therefore, the result are unpredictable. There is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skill in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. This specification provides only a starting point, a direction for further research.

7) the quantity of experimentation necessary;

The courts have interpreted undue experimentation as requiring "ingenuity beyond that to be expected of one of ordinary skill in the art" (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)). Additionally, the courts have determined that "... where a statement is, on its face, contrary to generally accepted scientific principles", a rejection for failure to teach how to make and/or use is proper (In re Marzocchi, 169 USPQ 367 (CCPA 1971). As such, the quality of experimentation necessary to identify and qualify all sequences that hybridize to the SEQ ID NO: 1 or2 under undefined conditions is undue.

8) the relative skill of those skilled in the art;

In view of the discussion of each of the preceding seven factors the level of skill in this art is high and is at least that of a PhD or a person with several years of experience in the art. As the cited art would point to, even with a level of skill in the art which is high, predictability of the results is not invariable.

In consideration of each of factors 1 – 8, it is apparent that there is undue experimentation because of variability in prediction of outcome that is not addressed by the present application disclosure, examples, teaching, and guidance presented. Absent factual data to the contrary, the amount and level of experimentation needed is undue.

a. Applicant argues that "stringent conditions" have an established meaning in the art. Applicant argues that one of skill in the art can easily determine identify the location of introns and exons of the genomic DNA. Applicant's arguments have been considered but are not persuasive. Stringency is a relative not defined in the art or in the specification and is considered so vague as no meaning may be derived from the term. For example, would an annealing temperature of 60 °C be regarding as stringent? Additionally, not all sequences that would hybridize to SEQ ID NO: 1 would have the same function of inducing oocyte maturation or modulating cell proliferation, and qualifying every sequence for such activity is considered undue experimentation. The rejection is maintained.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "stringent" in claim 39 is a relative term which renders the claim indefinite. The term "stringent" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of "stringent".

a. Applicant argues that stringent is well known in the art. Applicant's arguments have been considered but are not persuasive. Stringency is a relative not defined in the art or in the specification and is considered so vague as no meaning may be derived from the term. For example, would an annealing temperature of 55 °C, 60 °C or 72 °C be regarding as stringent? The rejection is maintained.

New Rejections

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 40 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant is also referred to the Guidelines on Written Description published

at FR 66(4) 1099-1111 (January 5, 2001) (also available at www.uspto.gov). The following passage is particularly relevant.

> The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between structure and function structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within a genus, one must describe a sufficient number of species to reflect the variation within the genus. What constitutes a "representative number" is an inverse function of the skill and knowledge in the art. Satisfactory disclosure of a "representative number" depends on whether one of skill in the art would recognize that applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. In an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus.

Claim 40 is directed to the genomic DNA that encodes the protein defined by SEQ ID NO: 3 or 4. The specification discloses the protein of SEQ ID NO: 3 & 4, and a general discussion of methods regarding how to isolate variants or homologs. The specification does not provide description of genomic DNA that would encode the proteins of SEQ ID NO: 3 or 4. The specification is silent as to the number and positioning of exons and introns, size or sequence of the genomic DNA, o even the location on the chromosome.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of

ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

With the exception of SEQ ID NOs: 1 & 2, the skilled artisan cannot envision the detailed chemical structure of the encompassed DNA, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only isolated nucleic acid molecules comprising the sequence set forth in SEQ ID NOs: 1 & 2, but not the full breadth of the claim, meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Conclusion

7. Claims 37, 38, 41-43, 45 and 47-48 are in condition for allowance.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan K Snedden whose telephone number is (703) 305-4843. The examiner can normally be reached on Monday - Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone number for regular communications to the organization where this application or proceeding is assigned is (703) 746-3975.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

SKS
September 23, 2003

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